REPRESENTATIVE GARY E. SHERMAN
74th Assembly District

State Capitol
P.O. Box 8953
Madison, WI 53708
(608) 266-7690
Toll-free: 1-888-534-0074
Fax: (608) 282-3674
E-mail: rep.sherman@legis.state.wi.us

District Address:
P.O. Box 157
Port Wing, WI 54865
715-774-3691

Representative Sherman Testimony on SB118, Prescription Drug Bill

Thank you, Chairman and Senators for the opportunity to present on this bill. I am sorry that I cannot attend personally, but I am unable to leave my district this week. (I swear that I am not on vacation.)

Let me begin with an anecdote.

A couple of years ago, a powerful prescription painkiller was taken off the market after several people died from its effects. It had been originally intended as a very specialized drug to be used in those limited circumstances where no other drug could suffice. In these extreme cases, the drug's hazards were factors that had to be taken into account in the prescribing doctor's exercise of professional judgment.

However, the drug company, in its unending greed for profits, heavily advertised the drug directly to consumers as though it were an exceptionally effective, but broadly appropriate, painkiller. The result was that the drug was massively overprescribed compared to its original purpose, resulting in unnecessary deaths. It was then taken off the market.

Thus, there were two bad results. The public was subjected unnecessarily to a dangerous drug that resulted in several deaths, and a potentially valuable tool for doctors to use in exceptional cases was lost, with additional harm to patients.

Prescription drugs are hazardous substances. We mandate that they cannot be consumed by individuals unless a doctor, exercising independent medical judgment, decides that it is appropriate and writes a prescription. We even have additional regulations that limit the circumstances under which a doctor may do that.

We do this to protect the public from doing themselves serious harm through their lack or understanding of the hazards of these chemicals.

When giant drug companies spend hundreds of millions of dollars advertising these same hazardous substances directly to consumers, they destroy the very protection that we seek to create by requiring prescriptions for these drugs in the first place.

There are a number of medical journal articles published in reputable, juried journals that document research which shows that this advertising has the effect that the companies hope for when they spend these outrageous amounts of money.

If a patient goes to a doctor and requests a particular drug, they are many times more likely to get that drug than if they simply go to the doctor and complain of symptoms. This is well documented.

Clearly, in these cases, the patient and not the doctor is making the decision about when this hazardous substance is being prescribed. This eliminates the doctor's independent medical judgment and defeats the entire purpose of these drugs being prescription drugs in the first place.

The result is that these advertisements pose a direct, well-documented hazard to public health and safety. They also represent a substantial portion of the skyrocketing cost of prescription drugs.

The Wisconsin Medical Society must have understood this when they voted at their annual meeting several years ago to oppose "direct to consumer" advertising of prescription drugs.

This bill addresses this problem in a carefully limited way. It forbids "direct to consumer" advertising of prescription drugs, but only within the limits of the U. S. Constitution.

In order to comply with the Constitution's restriction on our ability to regulate interstate commerce, this bill is narrowly drawn to only forbid such advertisements which are entirely in-state. Clearly, that will only directly eliminate a minority of these ads. However, as with our groundbreaking "do not call" legislation, which is subject to the same commerce clause limitations, this bill is intended to serve as a first strike in a national movement against this scourge.

The question of the First Amendment is also addressed in the manner in which this bill is drafted. Commercial speech is not like political speech. Commercial speech can be regulated if there is a compelling state interest and if the means are the least restrictive available.

In the past, federal courts have approved the regulation of tobacco and alcohol advertising, as well as comprehensive regulations of lawyer advertising in both Iowa and Florida. The key is for the legislature to make clear findings that there is a compelling public interest (in this case, the hazard to public health that is well documented in the medical literature) and to show that no lesser form of limitation will serve the need.

This legislation is drafted to make those legislative findings and is designed to survive an anticipated court challenge to its constitutionality.

"Direct to consumer" advertising of prescription drugs is bad for the public. It subjects people to unnecessary danger and it adds unreasonably to the cost of prescription drugs. It serves no socially useful purpose and good public policy requires that it be banned.

I hope, therefore, that you will take executive action on this bill quickly and move it forward for eventual passage.

Thank you again for bringing this before the committee.

Rep. Gary E. Sherman
74th Assembly District

State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

August 15, 2007

The Honorable Tim Carpenter, Chair
Committee on Public Health, Senior Issues, Long Term Care, and Privacy

Re: SB 118 advertising for prescription drugs.

Dear Senator Carpenter:

Thank you for permitting the Department of Agriculture, Trade & Consumer Protection the opportunity to testify for information regarding SB 118.

This bill is very confusing. The basic idea is that ads for prescription drugs are prohibited. However the bill lacks some key definitions, which leads to the potential for widely differing interpretations. This makes both administration of the law by DATCP and compliance by businesses difficult. Here are three examples of needed definitions.

A prescription drug ad is okay if it "is broadcast from or is mailed or shipped to the ultimate recipient of the advertisement from outside this state." When is an ad "broadcast from outside this state?" If CBS corporate sends a tape of the ad to its Madison affiliate and tells it to air sometime during the 10 PM news, and the local does that, was the ad broadcast from in or outside this state? What if the same ad is part of a CBS program, like 60 Minutes. Is that broadcast from inside or outside the state? The same is true for radio, satellite or cable broadcasts. How does one determine if it is broadcast from in the state, as the bill contains no definition.

A prescription drug ad is also ok if it is "mailed or shipped to the ultimate recipient of the advertisement from outside this state." Who is the ultimate recipient? Assume Newsweek ships from outside Wisconsin many magazines to Walgreen's, Barnes & Noble, etc. who put them on their shelves for consumers to buy. If Walgreen's is the ultimate recipient under the bill there is no violation. However, if the person who is going to buy and read the magazine is the ultimate recipient, then shipping them to Walgreen's, even from outside the state is a violation.

We understand that many national periodicals and newspapers are actually printed by large businesses, eg. Quad/Graphics, in Wisconsin and then distributed to Wisconsin locations and consumers (as well as being sent outside Wisconsin). If the "copy" comes from out of state, but is printed in state, is the product "shipped"

from Wisconsin or is it really "shipped" from out of state, like the New York Times is originated in New York? What does "shipped" mean in this bill?

Finally, no penalty is specified in the bill so it defaults to a criminal misdemeanor under Sec. 100.26, Stats., which calls for up to a $200 fine and/or 6 mos. in jail. As one can not put a corporation in jail, the fine of $200 is the likely penalty.

Thank you for this opportunity to comment on Senate Bill 118.

Respectfully,

Jim Rabbitt
Director
Bureau of Consumer Protection

Statement PhRMA

In Opposition to SB 118

August 15, 2007

Position: PhRMA opposes Wisconsin Senate Bill 118 which would prohibit pharmaceutical companies from disseminating direct-to-consumer (DTC) advertising in Wisconsin. The Food and Drug Administration (FDA) regulates DTC advertisements which preempts state laws.

The Pharmaceutical Research and Manufacturers of America (PhRMA) believes that current Food and Drug Administration (FDA) policies effectively regulate direct-to-consumer advertisements (DTCA). Last year alone, drug manufacturers invested more than $55 billion in research and development of new medicines; whereas, direct to consumer advertising accounts for less than 2 percent of the total spending for prescription medicines in the U.S.[1, 2]

DTCA Provides Valuable Educational Information to Patients

DTC advertising's overarching purpose is to inform and educate patients about treatable conditions, symptoms of illness, and available therapies. Research shows that communication with the general public about approved drug products through print, broadcast, and electronic media encourages productive dialogue between patients and their physicians. Nearly one in five patients reported speaking to a physician about a condition for the first time because of a DTC ad.[3] Furthermore, "[DTC advertising] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better informed decisions about their treatment options."[4]

Lack of compliance is a critical problem in achieving effective medical care. The World Health Organization states, "Poor adherence to long-term therapies severely compromises the effectiveness of treatment, making this a critical issue in population health both from the perspective of quality of life and of health economics."[5] According to Prevention Magazine, DTC ads encourage compliance with physician-prescribed treatment regimens. For example, a RXRemedy and Pfizer study found that patients who involve themselves in their health care by asking their doctor about a prescription drug they saw in a DTC advertisement are more likely to take their medication than those who do not. Furthermore, arthritis patients who have seen a DTC ad are 75 percent more likely to stay on their medication and patients treated for depression are 37 percent more likely to stay on their medication.[6]

DTCA Does Not Replace the Doctor-Patient Relationship

The physician or prescriber evaluates the benefits and risks contained in a drug's approved labeling, determines if the drug is appropriate for that patient, and gives the patient specific instructions and warnings specific to their condition when the drug is prescribed. The physician-patient relationship is essential to all medical treatment and can never be replaced by advertising. In fact, the National Medical Association (NMA) found that "Doctors are

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[1] Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2007 (includes PhRMA research associates and non-members).

[2] Harvard University and Massachusetts Institute of Technology, study of direct-to-consumer advertising (Washington, DC: The Henry J. Kaiser Family Foundation, June 2003).

[3] K. Aikin, *Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results,* 19 September 2002, http://www.fda.gov/cder/ddmac/Presentations/kithmcc2002out/sld001.htm (accessed 6 August 2004).

[4] Federal Trade Commission, *op. cit.*

[5] World Health Organization, *Adherence to Long-Term Therapies: Evidence for Action*, 2003, http://www.who.int/chronic_conditions/adherencereport/en (accessed 8 September 2004).

[6] Pfizer Inc and RxRemedy, Inc., *Impact of DTC Advertising Relative to Patient Compliance*, June 2001, http://www.pfizer.com/are/about_public/mn_about_dtcadsdoc. html (accessed 11 August 2004).

[illegible]

[illegible]

August 15, 1996

[illegible]

[illegible]

[illegible]

finding that [DTC] ads are helping patients talk to [doctors] about medical conditions they're at risk for...We must view [DTC ads] as one of the several tools that are potentially beneficial to the physician-patient dyad."

The FDA Oversees Prescription Drug Advertising

Unlike other types of advertisements, including advertisements from managed care companies, pharmaceutical DTC advertising must meet strict regulatory standards enforced by the federal FDA. Section 301 of the Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction into commerce or receipt in interstate commerce of any food, drug, device, or cosmetic that is "misbranded." Section 502(n) of the Act provides that a prescription drug shall be deemed misbranded unless all advertisements for that drug contain a "true statement" of: (1) the established (generic) name of the drug; (2) the ingredients of the drug; and (3) a brief summary relating to side effects, contraindications, and effectiveness. Such advertising must be truthful, present a fair balance of benefits and risks, and note that the medicine can only be purchased with a prescription. Furthermore, federal law requires that advertisements (both published and broadcast) include information about the major side effects and risks associated with the advertised drugs.[7]

Manufacturers must submit all advertising for a new medicine to the FDA for review prior to using the advertising and many manufacturers ask FDA to review advertising for older drugs. FDA has a variety of methods to enforce its regulation of advertising of prescription drugs, including requiring the manufacturer to conduct corrective advertising.

Direct-To-Consumer Advertising Is Protected Commercial Speech

The landmark U.S. Supreme Court decision, Central Hudson Gas & Electric Corp. v. Public Serv. Commission Of New York, established a four-part test to be applied by courts in determining the constitutionality of commercial speech restrictions.[8] First, the government may prohibit commercial speech only if the speech is inherently false or misleading or proposes an unlawful transaction. Second, the government must establish that it has a "substantial" interest in restricting speech. Third, the government must establish that its restriction directly furthers its objective – in other words, that the restriction "advances the Government's interest in a direct and material way." Fourth, the government must demonstrate that the governmental restriction is no more extensive than necessary to achieve the governmental interest. Not only are advertisements for prescription medicines not false or misleading, they are among the most regulated advertisements of any industry.

PhRMA Guiding Principles for DTC

PhRMA member companies take their responsibility to fully comply with FDA advertising regulations seriously. Patients, health care providers and the general public expect drug makers to do more than just meet these exacting legal obligations. To meet these expectations, PhRMA developed its own Guiding Principles on Direct-to-Consumer Advertising of Prescription Medicines to go further than required in regulating DTC advertising.

For the reasons set forth above and in an effort to provide as much information as possible for patients and physicians to together make informed decisions, PhRMA respectfully opposes Wisconsin SB 118.

[7] 21 CFR 202.1(l)1

[8] Central Hudson Gas & Elec. Corp. v. Public Serv. Commission, 447 U.S. 557 566 (1980).

Introduction

Many types of movement, including movement from managed care, require a physician's order. Physicians may also order physical therapy services for patients who are not homebound. Physical therapy and occupational therapy (OT) services are ordered by the Medical Doctor of Osteopathy (DO) or Medical Doctor (MD) who is managing the patient's medical care. Speech therapy services may be ordered by the MD or DO who is managing the patient's medical care or by a speech-language pathologist (SLP). Physical therapy, occupational therapy, and speech therapy services may be ordered by a physician, nurse practitioner, physician assistant, or clinical nurse specialist.

Medicare Coverage Criteria

Medicare Part B covers medically necessary physical therapy services, occupational therapy services, and speech therapy services. Medicare Part B covers these services when the patient is under the care of a physician, nurse practitioner, physician assistant, or clinical nurse specialist, and when the patient is under a plan of care that is established and reviewed by a physician, nurse practitioner, physician assistant, or clinical nurse specialist.

Medicare Coverage Criteria for PT

Medicare Part B covers physical therapy services when the patient is under the care of a physician, nurse practitioner, physician assistant, or clinical nurse specialist, and when the patient is under a plan of care that is established and reviewed by a physician, nurse practitioner, physician assistant, or clinical nurse specialist. The plan of care must be established before the therapy services are provided. The plan of care must be reviewed at least every 90 days. The plan of care must be signed by the physician, nurse practitioner, physician assistant, or clinical nurse specialist who is managing the patient's medical care.

Pharmaceutical Advertising

- Advertisers in this category spent an estimated $250,000 in the LaCrosse-Eau Claire television market in 2006.
- As a small market with limited retail growth, this revenue is not likely to be replaced in the near future.
- Adjacent television markets that "spill" into the LaCrosse-Eau Claire market include Rochester, Minneapolis/St. Paul, Duluth and Waterloo, Iowa.
- Viewers on the fringe of *our* market (Dunn county for example) will be exposed to pharmaceutical ads from *those* markets.

am 1290 WMCS
The Talk of the Town

My name is Don Rosette and I serve as General Manager of radio station 1290 WMCS in the group, the Milwaukee Radio Alliance. The sister stations are, WLDB-B93.3 and WLUM-102.1. I want to say good morning to the Committee and all those present today for this Hearing on Public Health. Thank you for the opportunity to speak.. I am here to echo the sentiments of my colleagues regarding Wisconsin Senate Bill 118. As I understand it, this Bill, if it ultimately clears the Senate and the Assembly would prohibit advertising for prescription drugs in our state-unless it emanates from an out-of-state source, such as, national radio and television networks.

Our radio and television stations are partners with network affiliations, and as such, would not be compensated for airing prescription drug communications. But, as been stated, almost 60 years ago, Congress gave to the United States Food and Drug Administration (FDA), the right and the power for prescription drug advertising. This piece of legislation is legal and is protected in every other state or territory in these United States. We would not like to see it repealed in Wisconsin.

Further, if Senate Bill 118 becomes law, other media outlets would still be able to freely direct them to the public.

There is nothing about this proposed legislation that is good for the Wisconsin broadcaster, and therefore we are asking that you stop today, further consideration of Wisconsin Senate Bill 118.Thank you very much.

Respectfully submitted,

Don Rosette

Don Rosette, CRMC
General Manager
1290 WMCS radio

4222 W. Capitol Drive, Milwaukee, WI 53216 Phone/Fax 414 444-1290 / 414 444-1409

PETER D. FOX
WNA Executive Director
Peter.Fox@WNAnews.com

WISCONSIN NEWSPAPER ASSOCIATION

...world's oldest press association, established 1853.

August 15, 2007

To: Members of the Senate Committee on Public Health, Senior Issues, Long Term Care and Privacy
From: Peter D. Fox, Executive Director, Wisconsin Newspaper Association

Subject: Senate Bill 118

Thank you for the opportunity for the Wisconsin Newspaper Association (WNA) to comment on 2007 Senate Bill 118 that would prohibit advertising for prescription drugs in Wisconsin. That is, unless the advertisement emanates from an out-of-state broadcast source such as a national television or radio network, on the Internet or from a publication published outside Wisconsin – such as *USA Today*, the *Chicago Tribune*, *The Wall Street Journal*, *New York Times*, *Time* or *Newsweek* magazine or a plethora of other publications.

WNA readily concedes the subject of prescription drug advertising – particularly for the so-called "boutique" drugs – and how it affects overall prescription drug pricing is a matter of great public interest. We understand much of the concern of the legislators who bring this proposal forward. WNA member newspapers across the state for years have published news stories to inform the public about how the cost of drug advertising affects consumer pricing. Indeed, our association applauds the conviction of the sponsors in raising the profile of this issue in the forum of public policy discussion.

Constitutionally, however SB 118 has fundamental, fatal flaws. The bill seeks to ban communication in Wisconsin which is legal and protected in every other state and territory of the United States. Second, the bill would forbid Wisconsin publishers and broadcasters from printing or airing what others could freely circulate in our state. Third, the bill would create impossible, logic-defying situations. For example, would Wisconsin publishers be able to accept national or regional newspaper inserts – the Sunday magazine supplement is just one product that comes to mind? What about the not-uncommon situation of advertising inserts printed in Illinois, Iowa or Minnesota but circulated in Wisconsin newspapers?

A few years back there was a parallel situation in Florida. The Florida Legislature imposed a sales tax on "services," which included in-state advertising.

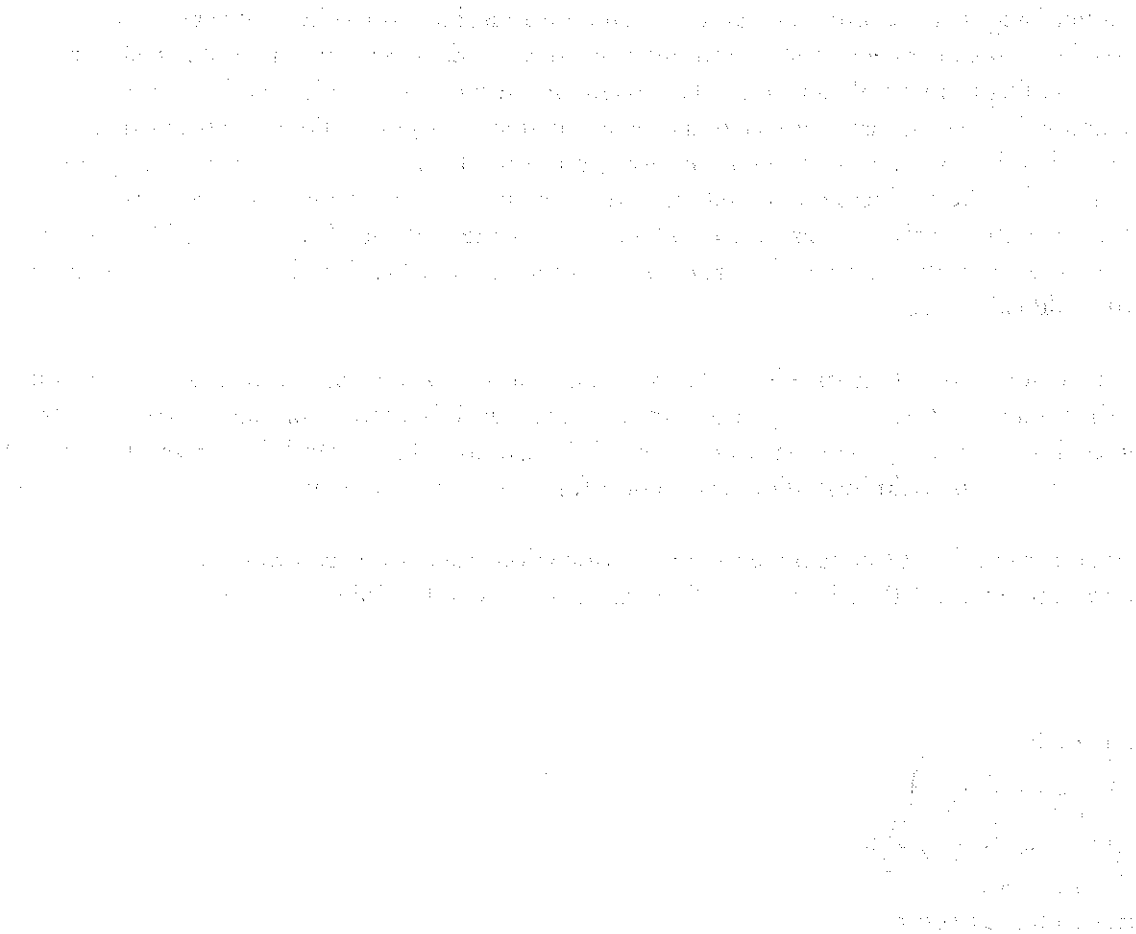
Advertising that was broadcast and delivered into Florida from other states was not taxed. To distinguish between in-state and out-of-state advertising was an impossible task for the Florida Department of Revenue. Also arising in the fracas was an issue of "multiple taxation" – that is, that a service could be taxed at several points along the way which is considered poor tax policy and unfair tax application. In the end, a huge wave of opposition emerged in the business community that resulted in the cancellation of conventions all over the state, the legislature was forced to backpedal, leaders of the effort in both Florida houses were ousted in the next election, and former Florida Gov. Mel Martinez reached the end of his political career.

The lesson here is that state legislatures cannot enact laws in isolation from what occurs in other states. Additionally it is important to understand that individual states cannot restrict speech protected by the First Amendment. We also note that in 1951 Congress gave the U.S. Food and Drug Administration jurisdiction for prescription drug advertising.

In summary, the Wisconsin Newspaper Association respectfully recommends that the committee reject SB 118 because of its constitutional and jurisdictional flaws.

Sincerely,

Peter D. Fox
Executive Director



Wisconsin Medical Society

Your Doctor. Your Health.

TO: Members, Committee on Public Health, Senior Issues, Long Term Care and Privacy
Senator Tim Carpenter, Chairperson

FROM: Mark Grapentine, JD & Jeremy Levin
Wisconsin Medical Society

DATE: August 15, 2007

RE: Senate Bill 118 – For Information Only

On behalf of 11,500 members statewide, the Wisconsin Medical Society thanks you for this opportunity to provide our thoughts on Senate Bill 118, related to advertising for prescription drugs. We appreciate Senator Carpenter and Representative Sherman's efforts to combat the high costs of health care.

The Wisconsin Medical Society supports appropriate legislative or regulatory programs that will ensure, to the greatest extent possible, the availability and affordability of prescription drugs for all Wisconsin patients. Further, the Society recognizes and supports efforts to control Direct-to-Consumer Advertising (DTCA) of prescription drugs and to strengthen federal efforts to more effectively regulate such advertising. The Society and the American Medical Association (AMA) have several related policies:

Society Policy:

DRU-009
Advertising Prescription Drugs: The Wisconsin Medical Society supports the physician-patient relationship as the most appropriate venue for determining the use of prescription drugs and devices.

DRU-011
Direct-To-Consumer Advertising: The Wisconsin Medical Society supports efforts to control Direct to Consumer Advertising of prescription drugs and American Medical Association actions to strengthen federal efforts to more effectively regulate such advertising.

AMA Policies:

H-105.988 Direct-to-Consumer Advertising (DTCA) of Prescription Drugs
1) Our AMA considers acceptable those product-specific direct-to-consumer advertisements (DTCA) that follow the guidelines for such advertisements that were developed by the AMA, in consultation with the FDA, in 1993. These guidelines also apply to DTCA of FDA approved medical devices, and are as follows:

(a) The advertisement should be disease-specific and enhance consumer education; (b) The ad should convey a clear, accurate and responsible health education message (i.e., information on the prevention or treatment of a disease, disorder, or condition); (c) In all cases, the ad should refer patients to their physicians for more information; (d) The ad should not encourage self-diagnosis and self-treatment, but should identify the consumer population at risk; (e). Discussion of the use of the drug product for the disease, disorder, or condition should exhibit fair balance; (f) Warnings, precautions, and potential adverse reactions associated with the drug product should be clearly explained so as to facilitate communication between physician and patient; (g) No comparative claims can be made for the product. In the interest of fair balance, alternative non-drug management options for the disease,

330 East Lakeside Street • PO Box 1109 • Madison, WI 53701-1109 • wisconsinmedicalsociety.org • Phone 608.442.3800 • Toll Free 866.442.3800 • Fax 608.442.3802

disorder, or condition can be included; (h) The brief summary information should be presented in language that can be understood by the consumer; (i) The advertisement must comply with applicable FDA rules, regulations, policies and guidelines as provided by their Division of Drug Marketing, Advertising and Communications; (j). The ad should be part of a manufacturer's education program that would include collateral materials to educate both physician and consumer; and (k) The manufacturer should not run concurrent incentive programs for physician prescribing and pharmacist dispensing.

(2) Our AMA opposes product-specific DTC advertisements, regardless of medium, that do not follow the above AMA guidelines.

(3) Our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical industry to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.

(4) Our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content, an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.

(5) Our AMA encourages physicians to be familiar with the above AMA guidelines for product-specific DTCA and with the Council on Ethical and Judicial Affairs (CEJA) Ethical Opinion E-5.015 and to adhere to the ethical guidance provided in that Opinion.

(6) Our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical industry to make policy changes regarding DTCA, as necessary.

(7) Our AMA advocates that direct-to-consumer prescription drug and medical device advertisements contain the disclaimer "Your physician may recommend other, appropriate treatments."

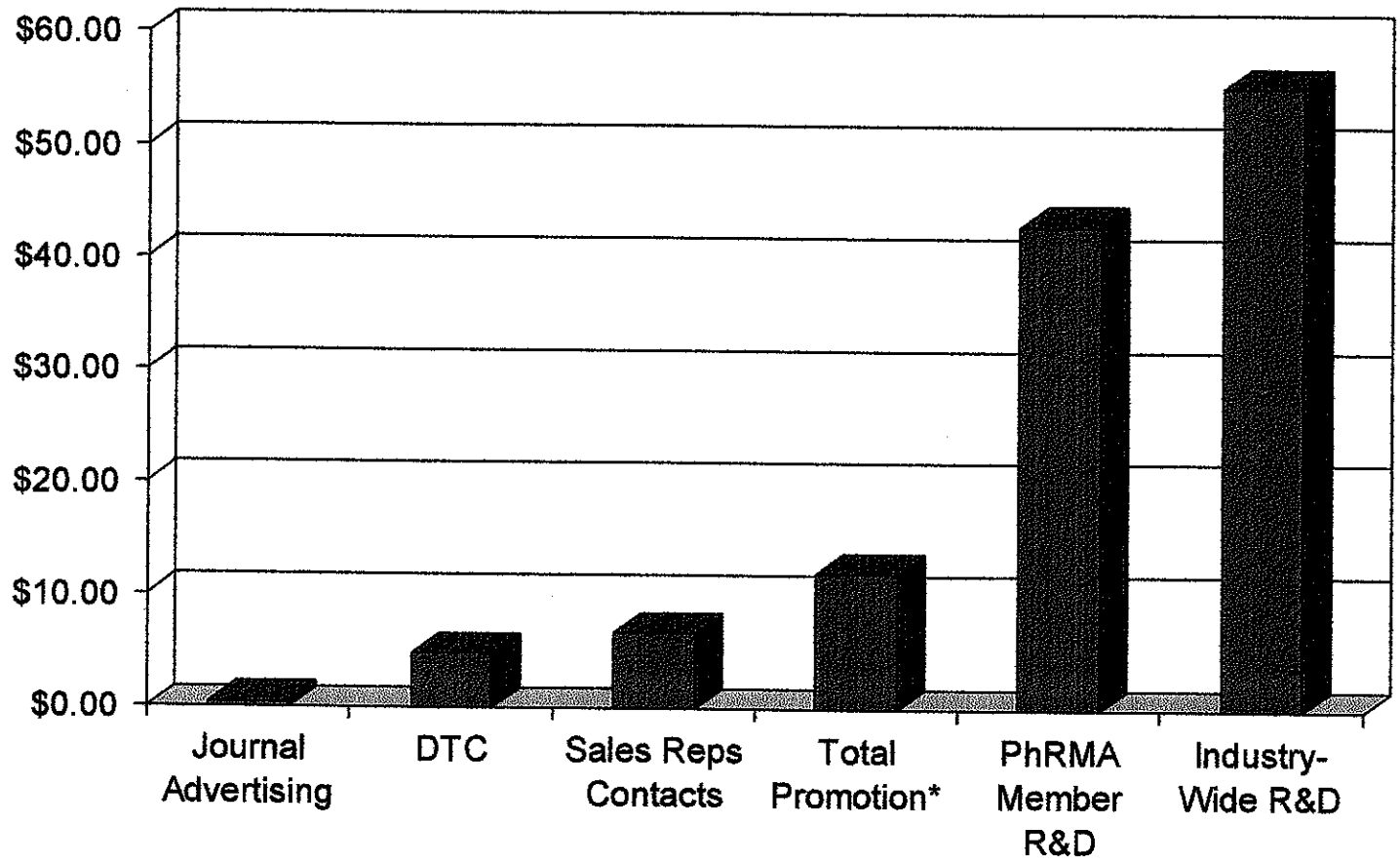
H-105.992 Pharmaceutical Advertising
The AMA supports calling upon the pharmaceutical industry to work with the AMA to promote print and electronic advertising that will educate the American public not only as to the beneficial effects of their over-the-counter products but also to the potential adverse effects of indiscriminate use of those same products.

With the escalating costs of prescription drugs, the impact DTCA has on those costs is worthy of debate. At the same time, the Society believes there is merit to the argument that this advertising does hold some positive effects by educating patients about certain medical conditions. Additionally, Society policy supports addressing DTCA on a national level.

As this debate continues, the Society believes in the sanctity of the physician-patient relationship in determining the most appropriate use of prescription drugs, and appreciates legislative efforts to this end.

Thank you again for this opportunity to provide this information. If you have any further questions or need additional information, please feel free to contact Mark Grapentine at markg@wismed.org or Jeremy Levin at jeremyl@wismed.org. Both can be reached at 608.442.3800.

Pharmaceutical Promotions and R&D, 2006



*Total Promotion refers to IMS Health data defined as: DTC, Retail Value of Samples, Office & Hospital Promotion (Sales Rep Contacts), and Journal Advertising. IMS did not publish 2006 data for Retail Value of Samples, so this was omitted from the calculation Total Promotion.
Note: R&D spending is estimated.
Sources: R&D Spending: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey,* 2007.
Promotional Data: IMS Health, *Integrated Promotional Services*™ and CMR, 7/2007.

Gráfico 1 - Evolução do PIB e da população brasileira (1980-2010)

Fonte: elaboração própria a partir de dados do IBGE.